Contracting for Biomedical and Behavioral R&D Services at the NIH

Charles Grewe

Director, Office of Acquisitions, DEA

National Institute of Allergy & Infectious Diseases

National Institutes of Health

U.S. Department of Health and Human Services

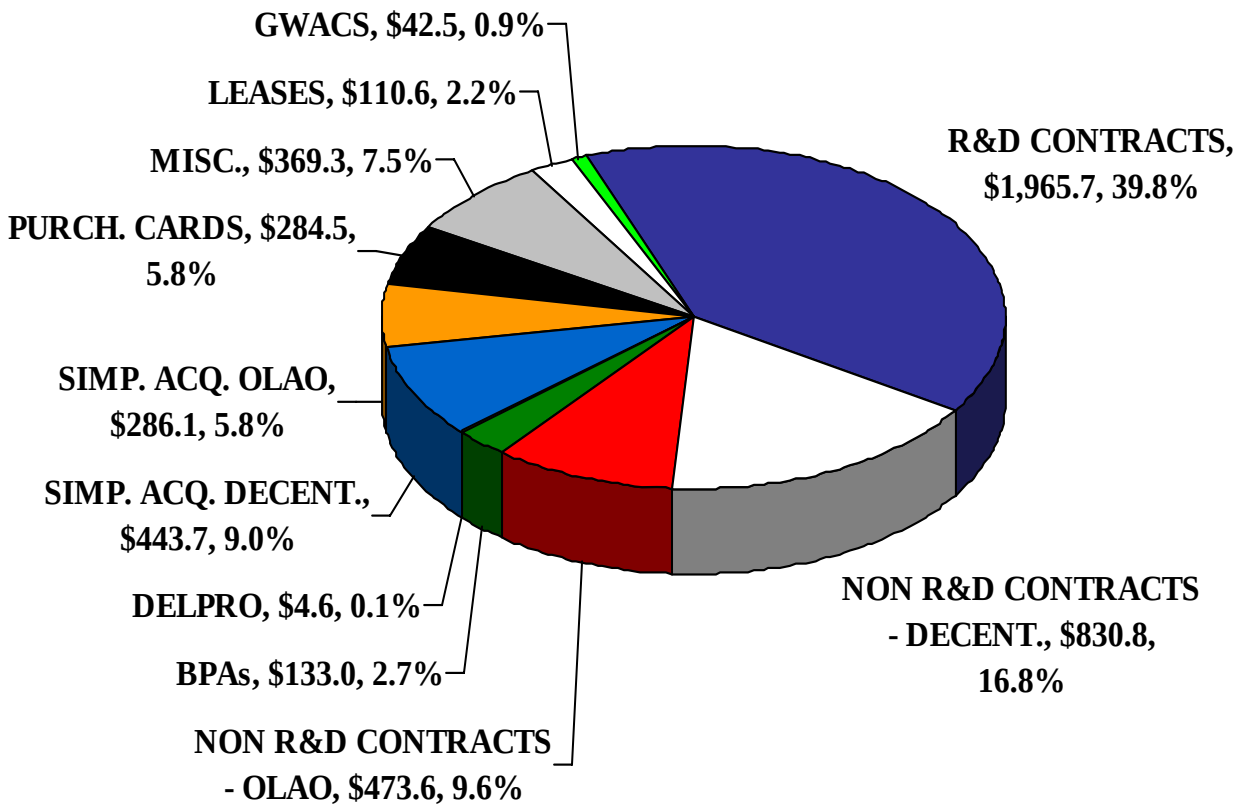
NIAID/Nordic Regional Research Networking Meeting, Helsinki, Finland / 10 May 2006

Acquisition at the NIH

The NIH buys goods and services from both domestic and international vendors

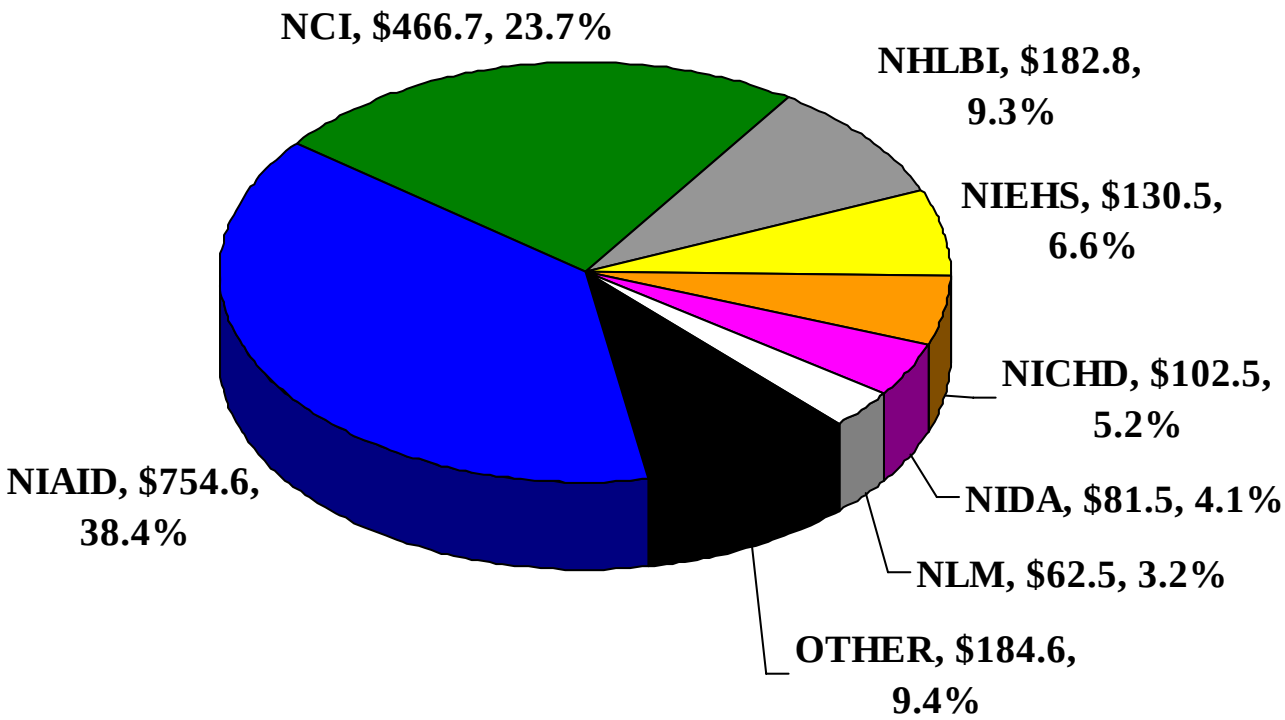
- basic office, medical, and information technology supplies
- construction services, M/O services
- services including management consulting, support services, and biomedical and behavioral research & development (R&D).

NIH FY 2005 ACQUISITIONS
$4.944.4 M
BY TYPE OF ACQUISITION



Shows Dollars in Millions and percentages of total dollars. Includes all acquisition FY 2005 funds obligated by NIH organizations.

NIH FY 2005 ACQUISITIONS
$1,965.7 M
R&D CONTRACTS



OTHER:	
OLAO R&D:	64.7, 3.3%
NIMH	37.1, 1.9%
NINDS:	25.9, 1.3%
NIDDK:	18.9 1.0%
NIAMS:	24.7, 1.3%
NIAAA:	13.3 , 0.7%

3/06

Shows Dollars in Millions and percentages of total dollars. Includes all R&D contract FY 2005 funds obligated by NIH organizations.

R&D Contracts

- Legal instrument used to purchase services for the direct benefit and use of Government.
- The Government states the work to be undertaken and generally retains an unlimited right to use data generated in performance.
- The Government has substantial programmatic oversight responsibility during the performance period.
- Frequently utilized for advance product development (regulatory and IP considerations) .

Regulations

- Federal Acquisition Regulations (FAR)
  http://farsite.hill.af.mil/vffara.htm
- Health and Human Services Acquisition Regulations (HHSAR)
  http://knownet.hhs.gov/acquisition/hhsar/Default.htm
- NIH Manual Chapters
  http://www1.od.nih.gov/oma/manualchapters/scripts/mcs/browse.asp
- NIAID Standard Operating Procedures
  http://www.niaid.nih.gov/ncn/sop/default.htm

Primary Method of Contracting for R&D

- **Negotiated Contracts with Cost Reimbursement Award** – The inherent uncertainties of R&D generally preclude award without discussion and require cost reimbursement funding arrangements.
- Technical merit is of paramount importance
- Past performance record considered
- Protection of human subjects and inclusion of women and minority study populations must be addressed as applicable in clinical research.
- Data sharing plan, IT system security, small business utilization, and cost

Government Team

A team approach to contract design, solicitation, award, and management

- Contracting Officer
- Project Officer
- Scientific Review Administrator and Technical Evaluation Committee (Peer Review Team)

Role of the Contracting Officer

- The CO is a warranted agent of the Government
- All pre-award communication directed to CO
- The only person with the authority to enter into, modify, or terminate contracts
- Relies upon the Project Officer (PO) for subject-matter expertise
- Primary relationship with Contractor's business representative

Role of the Project Officer

- Contracting Officer's Technical Representative
- Experienced in scientific and technical disciplines
- Responsible for monitoring the technical progress and recommending change to the CO
- Primary relationship is with the Contractor's Principal Investigator (PI)

Role of the Peer Review Team

1. Scientific Review Administrator
   - Government employee, expertise in a scientific discipline
   - Manages independent review process

2. Technical Evaluation Committee
   - Subject matter experts who review and evaluate merits of technical proposals.
   - Advise PO/CO regarding strengths and weaknesses of all technical proposals.

Acquisition Process

- Research question is identified
- Concept is developed and presented to NIAID Advisory Council

Acquisition Strategy

- Market Research
- Request for Proposals (RFP)
- Competitive Solicitation
- Independent Peer Review of proposal
- Negotiation with competitive offerors
- Final Proposal Revision
- Source Selection
- Award

Market Research

- The acquisition team investigates the present state of the art, critical technical limitations, and capacity by communicating with industry/academia.

- Key concepts and capabilities are learned without revealing specifics of Government’s requirement.

Request for Proposals (RFP)

- **Statement of Work** – Detailed technical description of work to be performed under contract.
- **Deliverables** – Reports, data, biological samples, software, anything the contractor will produce or develop under contract
- **Proposal Preparation Instructions** - Describes required proposal content, format, and information that is needed in the technical and business proposal. Tied to SOW and Evaluation Criteria.
- **Evaluation Criteria** – How technical proposal will be evaluated and scored

RFP table of Contents

Supplies or Services and Prices/Cost	Section B
Description/Work Statements	Section C
Packing, Marking and Shipping	Section D
Inspection and Acceptance	Section E
Deliveries or Performance	Section F
Contract Administration Data	Section G
Special Contract Requirements	Section H
Contract clauses	Section I
Attachments	Section J
Representations and Certifications	Section K
Instructions to Offerors – Technical & Business	Section L
Technical Evaluation Criteria	Section M

Competitive Solicitation

- The Government publicizes all contracting opportunities over $25,000 in the Federal Business Opportunities (FedBizOpps)

  http://www.fedbizopps.gov/

FedBizOpps notifies registered offerors by e-mail of new posted requirements and any modifications to existing requirements

- NIH also publishes all requirements in the NIH Guide for Grants and Contracts (similar to a trade journal).

  http://grants.nih.gov/grants/guide/index.html

A--NIAID Centers of Excellence for Influenza Research and Surveillance

General Information

Document Type:	Presolicitation Notice
Solicitation Number:	NIH-NIAID-DMID-BAA-07-20
Posted Date:	Sep 30, 2005
Original Response Date:	Feb 28, 2006
Current Response Date:	Feb 28, 2006
Classification Code:	A -- Research & Development
Naics Code:	541710 -- Research and Development in the Physical, Engineering, and Life Sciences

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, National Institutes of Allergy and Infectious Diseases, Contract Management Program 6700 B Rockledge Room 3214 MSC7612, Bethesda, MD, 20892-7612

Description

The Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) has a requirement to establish multiple Centers of Excellence for Influenza Research and Surveillance to conduct prospective animal influenza surveillance, internationally and domestically, and/or research on pathogenesis and host response. The solicitation method is a Broad Agency Announcement (BAA). Proposals may be submitted in one or both of the following Research Areas:

Research Area 1: The Contractor shall carry out an international and /or domestic animal surveillance program focused on virologic, epidemiologic, and disease surveillance with emphasis on the rapid characterization of influenza viruses with pandemic potential.

Research Area 2: The Contractor shall carry out a research program focused on two parts:
Part A: Determination of the molecular, ecologic and/or environmental factors that influence the evolution, emergence, transmission and pathogenicity of influenza viruses, including studies on animal influenza viruses with pandemic potential; and
Part B: Characterization of the immune response to influenza infection and /or vaccination to improve understanding of the immune correlates of protection and cross-protection.

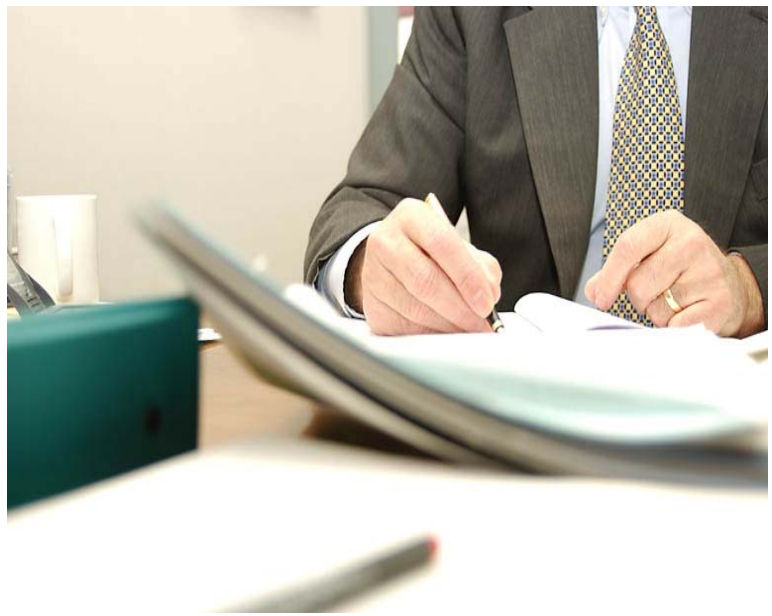
It is anticipated that up to four (4) cost-reimbursement, completion type contracts will be awarded for a period of up to seven (7) years beginning on or about November 13, 2006. RFP-NIH-NIAID-DMID-BAA-07-20 will be available electronically on or about October 14, 2005 and may be accessed through the NIAID Contract Management Program (CMP) Home Page by using the following electronic address and instructions:

Proposals will be due on or about February 28, 2006. Any responsible Offeror may submit a proposal for consideration by the Government. This advertisement does not commit the Government to award a contract. No collect calls will be accepted. See Government-wide numbered note 26. No facsimile transmissions will be accepted.

Proposal Preparation

- R&D requirements are “open” for a minimum of 45 days, typically 90-120 da.
- Separate Business Proposal and Technical Proposal
- Page limitations common
- Hard-copy and CD requested
- Common cut-off date and time
- Contractor’s Central Registry

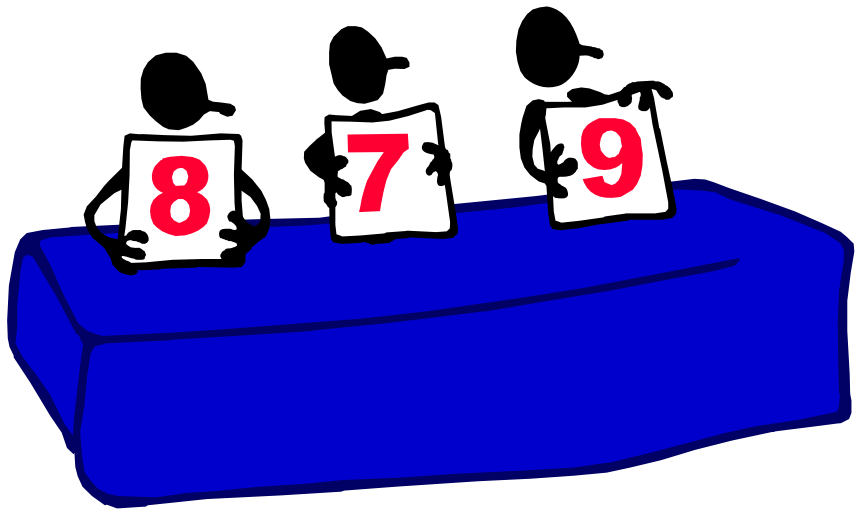
  http://www.ccr.gov/



Technical Evaluation Panel

An *ad hoc* peer review panel is appointed.

- The SRA screens potential reviewers for appropriate expertise and COI.
- CD copies of technical proposal delivered to reviewers.
- Primary and secondary reviewers lead the discussion of each proposal



Technical Evaluation

- The Technical Evaluation Panel evaluates each proposal against the evaluation criteria identified in Section M of the RFP.
- Proposals are not compared to each other.
- Each proposal is scored.
- Each proposal is determined to be technically “acceptable” or technically “unacceptable”.
- Technical comments are summarized and recorded in a Technical Evaluation Report
- Identifies strengths and weakness of each technical proposal

Technical Evaluation (other elements)

When applicable, the committee will also evaluate:

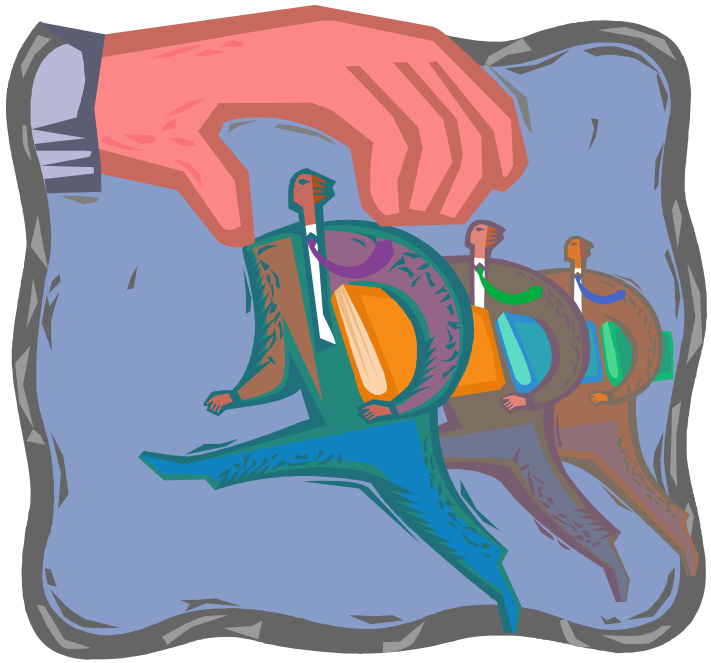
- Human subjects protection
- Inclusion of special populations in Clinical Research
- Animal Welfare
- Offeror's plan for sharing research data
- Direct cost realism

Preliminary Business Evaluation

- responsibility
- price evaluation / cost realism
- indirect rate / benefits
- past performance
- small and disadvantaged business inclusion

The Contracting Officer Establishes "Competitive Range"

- The contracting officer establishes the Competitive Range with the assistance of the project officer.
- The Competitive Range identifies those offerors who are the most highly rated. Only these offerors will be considered for award.
- Competitive Range is based on technical score, cost/price, and, any other factors identified in the RFP.

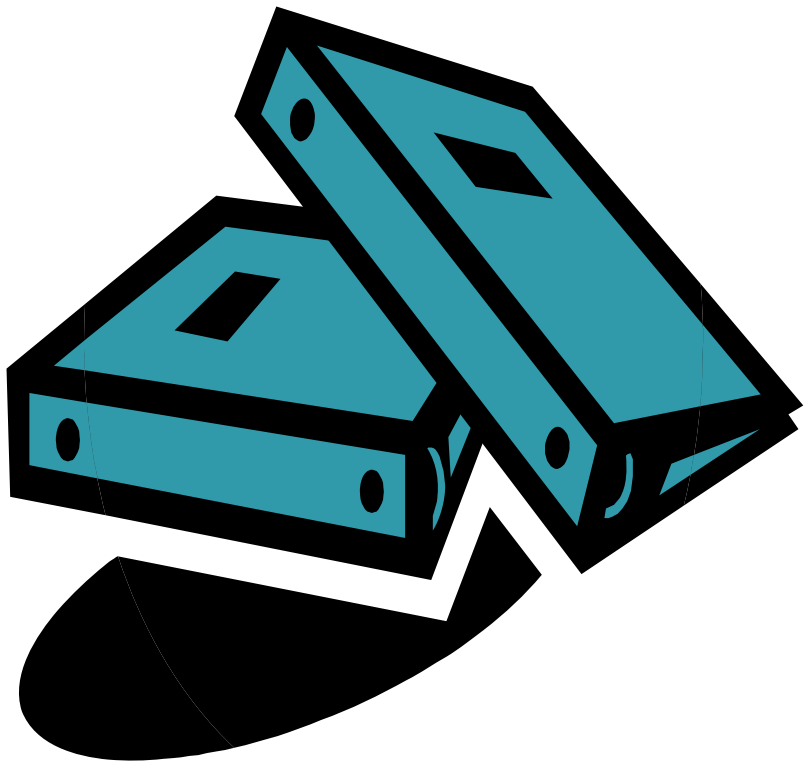


Negotiation / Discussions

- Contracting Officer is required to conduct “meaningful discussions” with all offerors in the Competitive Range.
  - Technical weaknesses
  - Cost/past performance
  - Special understandings

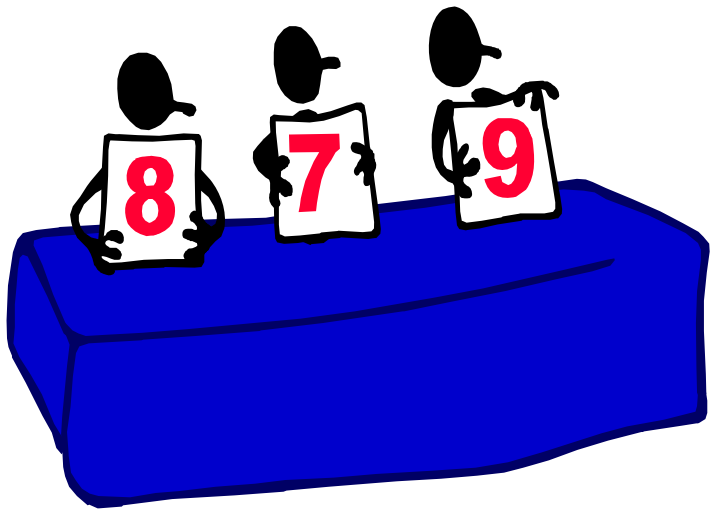
Final Proposal Revisions

- Negotiations end when all technical and business issues have been addressed.
- Revised proposals are requested at a common due date/time.
- Offerors may modify any aspect of their technical or business proposal.



Source Selection Board

- Revised technical proposals may be evaluated by a subset of original members of the Technical Evaluation Panel.
- The technical merit score may be revised in consideration of changes made during negotiations as reflected in the final proposal revision.
- The original Technical Evaluation Criteria (Section M) are used for revising proposal scores.
- Recommendation provided to the Contracting Officer



Source Selection

- The Contracting Officer ensures cost and business issues have been adequately resolved.
- The Contracting Officer determines offeror(s) selected for award based on all factors leading to the best value.

Contract Award

- Tailored contract terms and conditions, the estimated contract cost/price, and key personnel are written into the contract document.
- Contracts are signed by the contractor (Business rep.) and the USG (CO)

Critical Parts of the RFP

1. SECTION C – DESCRIPTION/SPECIFICATIONS
   Statement of Work – ARTICLE C.1 or Attachment 1
   Reporting Requirements/Deliverables – ARTICLE C.2

2. SECTION L – INSTRUCTIONS CONDITIONS and NOTICES
   Technical Proposal Instructions – ARTICLE L.
   Business Proposal Instructions – ARTICLE L.

3. SECTION M – EVALUATION FACTORS FOR AWARD

4. ATTACHMENTS
   Additional Technical Proposal Instructions – APPENDIX A
   Additional Business Proposal Instructions – APPENDIX B

http://www.fbo.gov/spg/HHS/NIH/NIAID/RFP%2DNIH%2DNIAID%2DDMID%2D07%2D11/Attachments.html

“Current ” Topics

- Clinical Trials Insurance
- Product Liability Insurance
- Legal representation at performance site
- Choice of Law
- Invoicing currency

NIH & NIAID Resources

NIH Home
http://www.nih.gov

NIAID R&D Office of Acquisitions
http://www.niaid.nih.gov/contract/default.htm

NIAID RFPs:
http://www.niaid.nih.gov/contract/rfps.htm

NIAID, OA SOPs
http://www.niaid.nih.gov/ncn/sop/work_flow_contracts.htm

Federal Resources

- **HHS Office for Human Research Protections**
  http://www.hhs.gov/ohrp/international/index.html#ethicalcde

- **International Compilation of Human Research Protections**
  http://www.hhs.gov/ohrp/international/HSPCompilation.pdf

- **Registration of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC)**
  http://www.hhs.gov/ohrp/assurances

- **FDA Center for Drug Evaluation and Research – International**
- **http://www.fda.gov/cder/audiences/iact/iachome.htm**

Strategic Plans for NIAID

- NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats, June 2005 (PDF)
- Biodefense Strategic Plan, 2002 (PDF)
- Health Disparities Strategic Plan, 2002-2006 (PDF)
- VRC Strategic Plan, 2001 (PDF)

Research Plans and Agendas

- NIAID Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis, 2001 (PDF)
- NIAID Biodefense Research Agenda for Category A Agents, 2002 (PDF)
- NIAID Biodefense Research Agenda for Category A Priority Pathogens, Progress Report, August 2003 (PDF)
- NIAID Biodefense Research Agenda for Category B and C Priority Pathogens, January 2003 (PDF)
- NIAID Biodefense Research Agenda for Category B and C Priority Pathogens, Progress Report, June 2004 (PDF)
- The NIAID Plan for Research on Immune Tolerance, 1998

Questions?

TECHNICAL EVALUATION CRITERIA
Example

The following evaluation criteria are used by the technical evaluation committee when reviewing technical proposals. The criteria listed below are in the order of relative importance with weights assigned for evaluation purposes.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A – Additional Technical Proposal Instructions OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

CRITERIA	WEIGHT
A. TECHNICAL APPROACH / METHODOLOGY: **Preclinical Development Services; Storage and Shipping; Technology Transfer**	**40 points**
B. QUALIFICATIONS OF PERSONNEL AND SAFETY	**30 points**
C. PROJECT MANAGEMENT and OPERATIONS: **Project Management; Subcontracting Acquisition and Management**	**15 points**
D. FACILITIES AND RESOURCES	**15 points**
TOTAL POSSIBLE POINTS:	**100 points**

APPENDIX A – ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

THE ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS PROVIDED BELOW REFLECT THE REQUIREMENTS OF THE RFP AND ARE MEANT TO PROVIDE A CLEAR UNDERSTANDING OF THE INTENT OF THIS SOLICITATION.

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF THE TECHNICAL PROPOSAL.

YOU ARE REMINDED THAT THE TOTAL PAGE LIMIT FOR THE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES, EXCLUDING APPENDICES PROVIDING STANDARD OPERATING PROCEDURES. PLEASE REFER TO THE FOLLOWING LINK FOR SPECIFIC PROPOSAL PREPRATION INSTRUCTIONS WITH REGARD TO PAGE LIMITATIONS: http://www.niaid.nih.gov/contract/eproposal.htm#electronic

SECTION 1: TECHNICAL APPROACH AND METHODOLOGY: Preclinical Development Services; Storage and Shipping of Reagents/Products; Technology Transfer

- Provide a table that for each type of preclinical service described in the Statement of Work under each of the five main categories, includes: a) information on past experience of the Offeror and/or the proposed subcontractor for each service; b) the pathogen and/or toxin that each activity was focused on; c) a brief description of the technical approach; d) whether the particular service has been qualified, validated, performed under GLP, or where applicable cGMP; e) the level of biocontainment required for the activity.
- Describe experience with select agents and how the expected licensure path involved the Animal Efficacy Rule (21 CFR Parts 314 and 601), and any subsequent or expected effect on preclinical development.
- Describe experience with and a plan for receiving, formatting, storing, and shipping compounds and biological agents and the management of associated records and documents.
- Describe experience with and a strategy for how technical transfers will be performed both into and out of the Contractor's or subcontractor's facility.
- Prepare a Project Plan as described in the Statement of Work (Project Planning, Initiation, Implementation, and Management) in response to the following two requests. Each Project Plan should not exceed 20 pages. Do not include SOPs.
- Propose a plan to manufacture 10 g of GMP bulk drug product (BDP) of a monoclonal antibody that has demonstrated in vitro and in vivo activity against ricin for use in preclinical studies and a Phase I clinical trial. Assume that you receive a GMP master cell bank; that qualified analytical assays and the manufacturing process were developed by another party that will transfer the cell bank, assays, and manufacturing process to your facility. Include the steps to obtain and transfer the master cell bank and the technology to your facility; manufacture, and characterize the BDP.
- Propose a project consisting of all relevant preclinical studies that would be required to support regulatory approval for clinical testing of an existing candidate two drug combination currently in Phase II clinical trials for a potential indication during pregnancy. Assume that one of the drug candidates has not undergone reproductive toxicity assessment. Include a listing of SOPs for proposed tests that would be conducted in order to comprehensively evaluate the drug combination.

SECTION 2: PERSONNEL AND SAFETY

- Document the qualifications, knowledge, experience, education, competence (as they relate to the Statement of Work), and availability of key personnel of the Contractor and of all proposed subcontractors, including recent experience with similar efforts. Limit CVs to 2-3 pages for key personnel. Qualifications and experience are supported by academic degree(s) and expertise, specialized training, and relevant work involving preclinical therapeutic development projects and services.

NIAID Role in Biodefense

- **NIAID'S ROLE IN BIODEFENSE**
- The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, conducts and supports much of the research aimed at developing new and improved medical tools against potential bioterrorism agents. Since 2001, NIAID has greatly accelerated its biodefense research program, launching several new initiatives to catalyze development of vaccines, therapies, and diagnostic tests.
- For example, in December 2004, an NIAID-funded clinical trial aimed at boosting the nation's flu vaccine supply began enrolling volunteers at four U.S. sites. In October 2004, NIAID announced $232 million in biodefense contracts for vaccine development against three potential bioterror agents: smallpox, plague, and tularemia. Also, an NIAID-funded study shed new light on how the smallpox virus attacks its victims.

- See our **list of fiscal year 2005 biodefense awards** for more information.

- **IDENTIFYING RESEARCH PRIORITIES**
- NIAID has set research priorities and goals for each microorganism that might be used as an agent of bioterrorism, with particular emphasis on "Category A" agents—-those considered by the Centers for Disease Control and Prevention to be the worst bioterror threats. NIAID's research agenda and strategic plan cover the following categories:
- **Basic biology**, understanding how microorganisms and their toxic products function and cause disease
- **Immunology and host response**, understanding how the human immune system interacts with and defends the body against potential agents of bioterrorism
- **Vaccines**, working closely with industry to create new and improved vaccines
- **Drugs**, closely working with industry to develop and test drugs to treat diseases that may result from a biological attack
- **Diagnostics**, developing devices or methods to quickly and accurately diagnose diseases caused by bioterrorism agents
- **Research resources**, establishing biosafety laboratories, databases, and other resources to help scientists conduct safe and effective biodefense research

- http://www3.niaid.nih.gov/Biodefense/About/niaids_role.htm